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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,733	12/30/2003	Dwight P. Morejohn	GUID-036	7537
36154 7590 06/11/2008 LAW OFFICE OF ALAN W. CANNON 942 MESA OAK COURT SUNNYVALE, CA 94086				
EXAMINER				
MAL HAO'D				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,733

Applicant(s)

MOREJOHN ET AL.

Examiner

HAO D. MAI

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 11, 13-30, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 2, 16-19, 21 and 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 13-15, 20, 22, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. **Claims 1 and 11** are objected to because of the following informalities:
 - The limitation "said lower portion" (line 6 of claim 1), should be "said lower spreader portion".

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. **Claims 1, 11, 13-15, 20, 22-23, and 45**, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - Claim 1 recites the limitation "the diaphragm and abdominal organs" (lines 6-7 of claim 1), which lacks antecedent basis.
 - Claim 11 recites the limitation "the same direction" (line 9 of claim 11), which lacks sufficient antecedent basis; and it is not clear which direction is being claimed as there are an indefinite number of directions, e.g. downward, towards the patient's head, etc., to which the free ends of the hooks and depressor surface are extending. Also, claim 11 recites the limitations "the sternal area" (line 4 of claim 11), "the diaphragm and abdominal organs" (line 6), and "the abdomen" (line 7), which lack antecedent bases.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicholas et al (5,967,974).**

Nicholas et al. disclose an access system (Fig. 3) comprising upper and lower spreader portions 126, 112, the spreader portions being positioned relative to each other producing a substernal space capable of accessing to the heart. The upper spreader portion 126 is capable of lifting the sternal area and comprising a hook 132 mounted to a retraction mechanism 128 via knob/swivel 128. Note that the circular base 128b allows the mounted hook 132 to turn around upon it at gap 128c, qualifying it a swivel (Fig. 8-9). The lower spreader portion 112 comprises depressor surface 112a capable of engaging the diaphragm and abdominal organs to depress the abdomen at the incision. The depressor surface 112a is shown to have a tongue depressor-like structure.

6. **Claims 11, 13, 20, and 45, are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips (4,865,019).**

Regarding claim 11, Phillips discloses an access system (Figs. 3-5) comprising upper and lower spreader portions 14, 13, being positioned relative to each other to produce a substernal space. The upper spreader portion 14 comprises a pair of hooks 48 for lifting the patient's sternal area, each of the pair of hooks having a free end portion independent of the other. The lower spreader portion comprising a depressor surface 30 underlying the pair of hooks (when in closed un-retracted position with the two connector arms 15 and 16 being

adjacent to each other). The depressor surface 30 is capable of engaging the patient's diaphragm and abdominal organs to depress the abdomen. The depressor surface 30 has a free end portion which is extending downward, substantially the same direction as the free end portions of hooks 48.

As to claim 13, the pair of hooks 48 each comprises a lifting surface capable of lifting the patient's sternal area (Fig. 4). As to claim 20, the upper spreader portion 14 is disclose to comprise a screw mechanism 44 for lifting and retracting the patient's sternum (Fig. 4; column 3 lines 36-52). As to claim 45, the depressor surface 30 has a tongue depressor-like structure.

7. Claims 11, 13, and 45, are further rejected under 35 U.S.C. 102(b) as being anticipated by Shulman et al. (4,991,566).

Regarding claim 11, Shulman et al. disclose a device 11 capable of providing a transabdominal access for a patient comprising: an upper and lower spreader portions 12 and 13 respectively, being positioned relative to each other and capable of producing a substernal space (Figs. 1 and 3). The upper spreader portion 12 includes a pair of hooks 21 capable of lifting the patient's sternal area at the incision; each of the pair of hooks 21 having a free end portion independent of the other. The lower spreader portion 13 comprises a depressor surface 21 underlying the pair of hooks 21 of upper spreader portion 12. The depressor surface 21 of lower spreader portion 13 is capable of engaging the diaphragm and abdominal organs to depress the abdomen and has a free end portion that is extending in substantially the same direction a the free end portion of hooks 21 of upper spreader portion 12.

As to claims 13 and 45, each of the pair of hooks 21 comprises a lifting surface capable of lifting the patient's sternal area; and the depressor surface 21 has a tongue depressor-like structure.

Note that it has been held that the recitation that an element is "configured to" perform a function is not a positive structural limitation in an apparatus claim but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. With all the claimed structures and their capabilities of performing the claimed functions shown, Shulman et al. qualifies as prior art even though it is for a mouth-prop device. Calling/claiming a structure "a transabdominal access system" is merely an intended use, which also does not constitute a limitation in any patentable sense.

8. Claims 11, 13, 20, and 45, are further rejected under 35 U.S.C. 102(b) as being anticipated by Santilli et al. (6,099,468).

Regarding claim 11, Santilli et al. disclose a transabdominal access system 10 comprising: an upper spreader portion 46 and a lower spreader portion 22 being positioned relative to each other to produce a substernal space (Figs. 1-2). The upper spreader portion 46 includes a pair of hooks 78 and 80 each having a free end portion independent of the other and capable of lifting the patient's sternal area. The lower spreader portion 22 comprises depressor surfaces 14 and 82 both underlying the pair of hooks (when portion 22 is adjusted to be in near or adjacent portion 20). The depressor surface 14 is capable of engaging the diaphragm and abdominal organs and has a free end that is extending downward, substantially the same direction as the free ends of hooks 78 and 80.

Regarding claim 13, 20 and 45, Santilli et al. further disclose: each of the pair of hooks comprising a lifting surface capable of lifting a patient's sternal area; the upper spreader portion 46 comprising a retraction mechanism 54/66 capable of lifting the rib cage by adjusting the rods 84 of hooks 78 and 80; and the depressor surfaces 14 and 82 both having a tongue-depressor-like structure (Figs. 1-2).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 11, 13-15, and 22, are (further) rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholas et al (5,967,974) in view of Phillips (4,865,019).**

Regarding claim 11, Nicholas et al. disclose an access system (Fig. 3) comprising upper and lower spreader portions 126, 112, the spreader portions being positioned relative to each other producing a substernal space. The upper spreader portion 126 comprises a hook 132 having a free end capable of lifting the sternal area. The lower spreader portion 112 comprises depressor surface 112a. When in closed un-retracted position with portion 126 being adjusted most towards portion 112, depressor surface 112a is underlying hook 132 (Figs. 2-3; best shown in Fig. 2 if/when 112 and 132 are adjacent each other). The depressor surface 112a has a free end portion which is extending downward, substantially the same direction as the free end portion of hook 132.

Nicholas et al. disclose the invention substantially according to claim 11 except for a pair of hooks. Philips discloses an access system comprising a pair of hooks 48. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the upper spreader portion of Nicholas with a pair of hooks, as taught by Phillips, in order to spread the forces evenly along the incision.

As to claims 13-15, and 22, Nicholas et al.'s hook 132 is shown to comprise: a lifting surface for lifting the patient's sternal area; first and second side portions (of frame 110) being

positioned between and integrally connected to upper and lower spreader portions 126, 112; and a screw mechanism 128 capable of lifting and retracting the sternum.

Response to Arguments

11. Applicant's arguments filed 01/17/2008 have been fully considered but they are not persuasive and/or moot in view of new ground(s) of rejection. Regarding 102 rejection of claims 1 and 44 under Nicholas, applicant asserts that Nicholas' structure 128 is not a swivel. The examiner disagrees; the mounted hook 132 is capable of turning around upon knob/swivel 128 at gap 128c and cut-out 130 or valley 126 when knob/swivel 128 is loose, thus qualifying knob 128 being a swivel.

Regarding applicant's arguments that Phillips does not disclose upper and lower portions and a swivel, Phillips clearly shows in Figure 1 a portion 14 that is above/upper of portion 13. As for the swivel, applicant did not claim a swivel in claim 11 which was rejected under Phillips. The newly added limitations "the depressor surface underlying the hooks... [and] the free ends of the depressor surface and the hooks extend in substantially the same direction" have failed to overcome Phillips (see rejection above).

The newly amended claim(s) are also further rejected under new ground(s) of rejections under Shulman and/or Santilli.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing

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date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Hao D Mai/
Examiner, Art Unit 3732**

/Cris L. Rodriguez/

Supervisory Patent Examiner, Art Unit 3732